

NUMB25- lidocaine 5% cream
Ebanel Laboratories, Inc

Active Ingredient Purpose

Lidocaine 5%Local Anesthetic

Uses

- For the temporary relief of local and anorectal itching and discomfort associated with anorectal disorders and anorectal inflammation.
- For the temporary relief of pain, burning and soreness.

Warnings (For external use only)

- If condition worsens or does not improve within 7 days, consult a doctor.
- Do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, consult a doctor promptly.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.
- Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

Directions

- Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Children under 12 years of age: consult a doctor.
- Apply externally to the affected area up to 6 times daily.

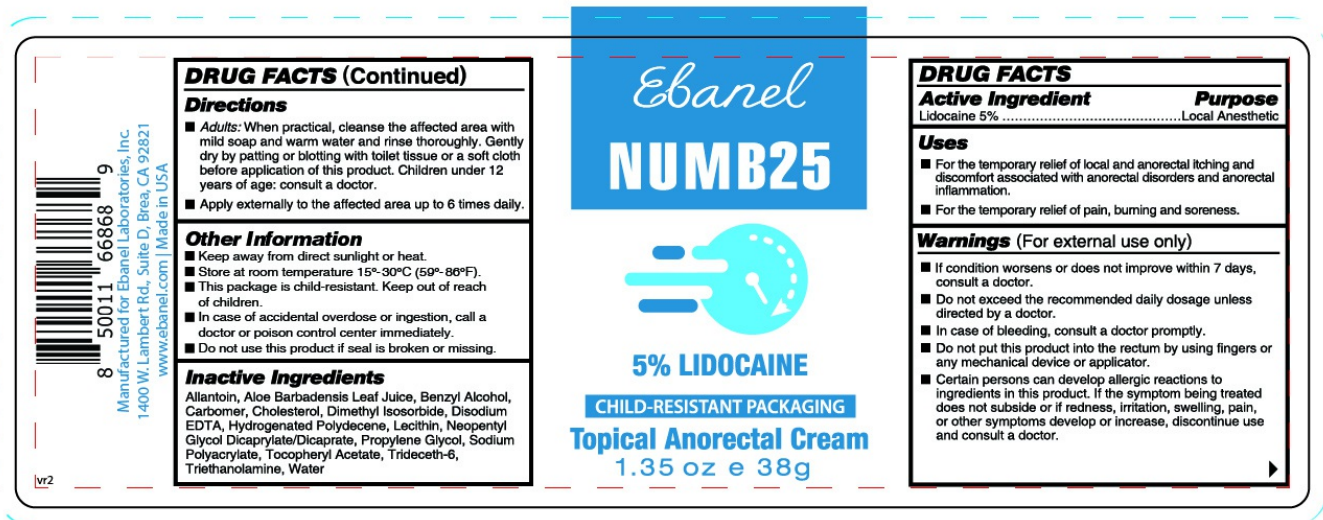
Other Information

- Keep away from direct sunlight or heat.
- Store at room temperature 15°-30°C (59°-86°F).
- This package is child-resistant. Keep out of reach of children.
- In case of accidental overdose or ingestion, call a doctor or poison control center immediately.
- Do not use this product if seal is broken or missing.

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Dimethyl Isosorbide, Disodium EDTA, Hydrogenated Polydecene, Lecithin, Neopentyl Glycol Dicaprylate/Dicaprate, Propylene Glycol, Sodium Polyacrylate, Tocopheryl Acetate, Trideceth-6, Triethanolamine, Water

Purpose.....Local Anesthetic



NUMB25

5% LIDOCAINE

CHILD-RESISTANT PACKAGING

Topical Anorectal Cream

1.35 oz e 38g

NUMB25			
lidocaine 5% cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72654-035
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	50 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)			
CHOLESTEROL (UNII: 97C5T2UQ7J)			
HYDROGENATED POLYDECENE (1500 CST) (UNII: 4YI0729529)			
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)			
WATER (UNII: 059QF0KO0R)			
TRIDECETH-6 (UNII: 3T5PCR2H0C)			

CARBOMER (UNII: 0A5MM307FC)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
ALLANTOIN (UNII: 344S277G0Z)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72654-035-01	38 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	05/13/2025	

Labeler - Ebanel Laboratories, Inc (079352161)

Registrant - Clinical Resolution Laboratory, Inc (825047942)

Establishment

Name	Address	ID/FEI	Business Operations
Clinical Resolution Laboratory, Inc.		825047942	manufacture(72654-035)

Revised: 5/2025

Ebanel Laboratories, Inc